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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,020	06/28/2005	**Kenji Fujii**	Q88147	4034

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EXAMINER	
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ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,020	FUJII ET AL.	
	Examiner	Art Unit	
	LESLIE A. ROYDS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 28-38 are presented for examination.

Applicant's Amendment filed March 16, 2009 has been received and entered into the present application.

Claims 28-38 are pending and under examination. Claim 38 is newly added. Claims 28-30 are amended.

Applicant's arguments, filed March 16, 2009, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claims 28 and 29 specify that the fatigue is physical exhaustion caused by exercise or fatigue caused by aging. Present claim 36 specifies that the fatigue is physical exhaustion during or after sickness. Present claim 37 specifies that the fatigue is muscle fatigue.

In particular, it is unclear how instant claims 36 and 37 (which, respectively, specify that the fatigue is physical exhaustion during or after sickness or that the fatigue is muscle fatigue) are intended to further limit instant claims 28-29, which each specify that the fatigue is physical exhaustion caused by exercise or fatigue caused by aging. Independent claims 28-29 clearly specify that the fatigue is either (1) physical exhaustion caused by exercise or (2) fatigue caused by aging and the dependent limitations of

physical exhaustion during or after sickness as recited in instant claim 36 or muscle fatigue as recited in instant claim 37 do not further narrow the scope of subject matter circumscribed by instant claims 28-29. Accordingly, one of ordinary skill in the art at the time of the invention would not have been reasonably apprised of the subject matter for which Applicant is presently seeking protection. Clarification is requested.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

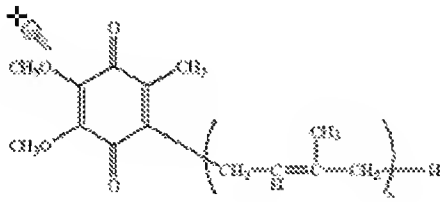
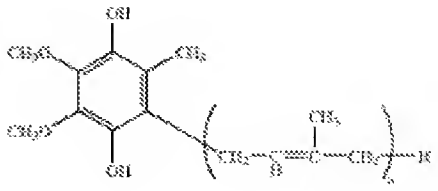
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28-35 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujii et al. (WO 2002/092067; 2002), citing to U.S. Patent Application Publication No. 2004/0115181 (2004) for an English translation, in view of Wilson et al. ("Exertional Fatigue Due to Skeletal Muscle Dysfunction in

Patients with Heart Failure", *Circulation*, 1993; 87:470-475), each already of record, and further in view of newly cited Remington's Pharmaceutical Sciences (Fifteenth Edition, 1980; p.712).

For the purposes of examination, U.S. Patent Application Publication No. 2004/0115181 A1 to Fujii et al. (Published June 17, 2004) will be relied upon for an English translation of the WO 2002/092067 reference relied upon as the basis for the present rejection. The '181 publication is the publication under 35 U.S.C. 122(b) of U.S. Patent Application No. 10/476,208, which is the U.S. National Stage (371) entry of PCT/JP02/04476, of which WO 2002/092067 is the International WIPO Publication of the same and is, thus, expected to contain the same subject matter. Reliance upon this document is in accordance with the MPEP at §901.05, which states, "It is possible to cite a foreign language specification as a reference, while at the same time citing an English language version of the specification with a later date as a convenient translation if the latter is in fact a translation." For clarity of the record, Applicant is notified that the page and paragraph numbers cited herein the instant rejection refer to the '181 publication and not the '067 publication.

Fujii et al. teaches a composition for transmucosal administration comprising an oxidized coenzyme Q of the formula  , wherein n represents an integer of 1 to 12, and/or reduced coenzyme Q of the formula  , wherein n also represents an integer or 1 to 12 (p.1, para.[0007-0009]), wherein coenzyme Q with 10 side chain repeating units (i.e., an oxidized coenzyme Q10 and reduced coenzyme Q10) are preferably used (p.2, para.[0016]),

wherein the total content of the above oxidized and reduced coenzyme Q amounts to 0.0001-99% by weight of the total composition (p.1, para.[0010]). Fujii et al. further teaches a method for treating, *inter alia*, cerebral infarction, heart failure, etc. (p.2, para.[0023]) comprising applying the composition for transmucosal administration to human or animal mucosa with a disease (p.5, cl.18), such as, *inter alia*, to the oral mucosa (i.e., "orally" as in newly added claim 38; p.1, para.[0011]), using, for example, an oral mucosal applicator, toothpaste or drop (p.2, para.[0019]), wherein the composition may be used in humans (i.e., a vertebrate, as well as mammal, as in instant claims 32-33), including aged persons (as in instant claim 35; p.4, para.[0042]), dogs, cats, race horses, cows, horses, pigs, rabbits, rats, mice, birds and the like (p.1, para.[0010]).

Fujii et al. fails to specifically teach the treatment of animals in a state of fatigue for reducing fatigue, particularly wherein the fatigue is physical exhaustion due to exercise (claims 28-29) or that the coenzyme composition is directly applied to skin (claim 31).

Wilson et al. teaches that patients with heart failure are frequently limited by exertional fatigue during both normal daily activities and maximal exercise testing and further describes a study of 34 patients with heart failure subjected to exercise for determining whether exertional fatigue is due to skeletal muscle dysfunction or reduced muscle flow (abstract). Wilson et al. teaches that all of the studied patients terminated exercise due to leg fatigue and concluded that a substantial percentage of patients with chronic heart failure develop exertional fatigue as a result of skeletal muscle dysfunction (abstract).

In view of such teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention that the disclosed coenzyme Q formulation of Fujii et al. would have been reasonably expected to exert the same or substantially equivalent efficacy in the reduction of fatigue in a patient in a state of fatigue wherein the fatigue is physical exhaustion from exercise because: (1) the composition of Fujii et al. was known to have efficacy in treating patients that suffer from heart failure and (2) a significant proportion of patients that have heart failure suffer from concomitant exertional

fatigue during exercise. Fujii et al. provides the clear teaching that the instantly claimed coenzyme Q formulation (i.e., comprising an oxidized and reduced form of coenzyme Q) is, in fact, effective for treating all heart failure patients, i.e., 100% of patients with heart failure, without exclusion. Of this entire population of heart failure patients, Wilson et al. provides the factual extrinsic evidence demonstrating that a subpopulation of heart failure patients also suffers concomitantly from concomitant exertional fatigue during exercise. Accordingly, the suggestion of Fujii et al. to use the claimed coenzyme Q formulation for treating any heart failure patient is a clearly suggestion to use it in any subpopulation of heart failure patients, such as those patients also suffering from concomitant exertional fatigue during exercise, with the reasonable expectation of the same (or at least substantially equivalent) level of efficacy in treating this subpopulation of patients as would be expected in the treatment of heart failure patients *per se*. Furthermore, since products of identical composition cannot have mutually exclusive properties when administered under identical conditions, or, as in the present case, the same host, whatever effect(s) the instantly claimed coenzyme Q formulation has in reducing fatigue in an animal in a state of fatigue wherein the fatigue is physical exhaustion from exercise must necessarily be present in the method disclosed by Fujii et al., absent factual evidence to the contrary. See MPEP §2112.

Remington's Pharmaceutical Sciences teaches that, although the skin and mucous membranes differ considerably in structure and function, they are similar in penetrability to chemical agents and in their response to certain physical and pharmacological stimuli (col.2, para.1, p.712). Remington's further teaches that many of the topical drugs disclosed therein can be applied to both types of surfaces, unless there is a contraindication for their application to mucous membranes and must be applied to the skin surface only (col.2, para.1, p.712).

One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to modify Fujii et al., who teaches the application of the disclosed coenzyme Q formulation comprising both a reduced and an oxidized coenzyme Q compound to the mucosal surface, by applying

the disclosed coenzyme Q formulation directly to the skin as required by the instant claims because the skin and mucous membranes, though different in structure and function, have similar chemical penetrability to chemical agents and exhibit similar response to pharmacological stimuli as evidenced by Remington's and, thus, would have been reasonably expected to function as interchangeable routes of administration for predictably providing substantially equivalent absorption of the active composition, absent factual evidence to the contrary. Furthermore, one of skill in the art would have had a reasonable expectation of successfully applying the formulation of Fujii et al., formulated for transmucosal administration, directly to the skin because Remington's teaches that agents formulated for mucosal administration can be equally applied to the skin for substantially identical pharmacologic effect, but that drugs formulated for application to the skin may not necessarily be acceptable for mucosal administration. Accordingly, since the formulation of Fujii et al. is already acceptable for mucosal administration, the skilled artisan would have reasonably expected that it would also have been acceptable for administration to skin, absent factual evidence to the contrary.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that there is physiological fatigue, which manifests in a healthy individual, and pathological fatigue, which manifests in patients with a physical disorder. Applicant submits that the object of the instant invention is the reduction of physiological fatigue rather than reduction of extreme fatigue due to disease as taught by Fujii et al. Applicant alleges that the reference to Fujii et al. does not teach the instant objective of reducing physiological fatigue as instantly claimed.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Though Applicant argues that the instant claims treat "physiological fatigue" and not "pathological fatigue" such as that which would result from a disease, the instant claims are not so limited

in this regard. The claims circumscribe the treatment of animals in a state of fatigue wherein the fatigue is physical exhaustion caused by exercise or fatigue that is caused by aging, but fails to specify that the fatigued animal is healthy and free from disease (i.e., "physiological fatigue" as described by Applicant). In other words, Applicant is arguing that the claimed invention is directed to the treatment of fatigue resulting from physical exhaustion caused by exercise in healthy individuals and not in individuals that suffer physical exhaustion caused by exercise wherein a concomitant disease may be present that contributes to said fatigue, but the claims fail to recite any limitations directed to the treatment of animals or patients that are otherwise "healthy". Thus, in response to Applicant's argument that the references fail to show certain features of Applicant's invention, i.e., specifically, that the animal is healthy and suffers from "physiological fatigue", not fatigue that may result from disease, it is noted that this feature upon which Applicant relies is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

For these reasons *supra*, and those previously made of record at p.8-11 of the Office Action dated December 16, 2008, rejection of claims 28-30 and 32-38 is proper.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Status of Rejections

Applicant is notified that the following rejections have been withdrawn pursuant to Applicant's amendments to the claims presented in the papers filed March 16, 2009:

(1) the rejection of instant claims 28-30 and 32-35 over claims 18-19 of U.S. Patent Application No. 10/275,882;

(2) the rejection of instant claims 28-30 and 32-35 over claims 6 and 15-28 of U.S. Patent Application No. 11/029,493;

(3) the rejection of instant claims 28-30 and 32-35 over claims 1-18 of U.S. Patent Application No. 11/315,201;

(4) the rejection of instant claims 28-30 and 32-35 over claims 13-24 of U.S. Patent Application No. 11/909,966;

(5) the rejection of instant claims 28, 30 and 32-35 over claims 9-12 of U.S. Patent Application No. 10/505,523;

(6) the rejection of instant claims 28-36 over claim 5 of U.S. Patent No. 6,184,255; and

(7) the rejection of instant claims 28-36 over claims 3-16 of U.S. Patent No. 7,015,252.

Claims 28, 30 and 32-33 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 6 and 10-19 of U.S. Patent Application No. 11/596,059, for the reasons of record set forth at p.13 of the previous Office Action dated December 16, 2008, of which said reasons are herein incorporated by reference.

Newly amended claim 28 remains properly included in the instant rejection because the copending anti-fatigue composition is defined as a composition for effecting recovery from physical fatigue due to exercise or improving a tendency toward getting tired because of aging (see p.1, l.12-16) and, thus, the method for treating fatigue using such a composition as provided for in copending claim 6

clearly circumscribes its use in a animal suffering from physical fatigue due to exercise or fatigue resulting from aging, as now instantly claimed. Please note that, in the instant case, the disclosure of the copending patent application is being relied upon solely to define the meaning of the term "anti-fatigue composition", which is consistent with the MPEP at §804, which states, "The specification can be used as a dictionary to learn the meaning of a term used in the patient claim. *Toro Co. v. White Consol. Indus., Inc.* 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999)."

Applicant states that, since the copending application(s) have not yet issued as patents, he defers responding to the rejection(s).

Insofar as the copending application has not issued as a patent, the instant claims are not in condition for allowance and Applicant has not provided a Terminal Disclaimer and/or remarks directed to the propriety of the instant rejection, the rejection is maintained for the reasons *supra* and those already of record.

Conclusion

Rejection of claims 28-38 is proper.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the

mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE A. ROYDS whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

May 12, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614